

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



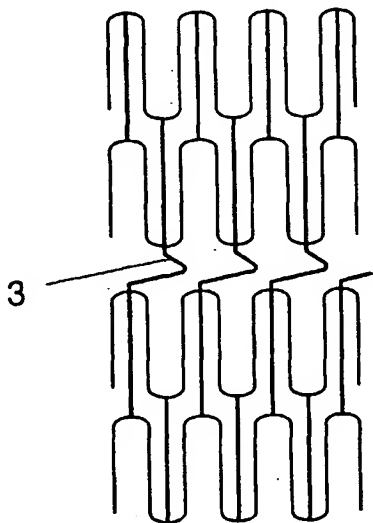
(43) International Publication Date
29 November 2001 (29.11.2001)

PCT

(10) International Publication Number
WO 01/89417 A1

- (51) International Patent Classification⁷: **A61F 2/06** (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (21) International Application Number: PCT/KR01/00833
- (22) International Filing Date: 21 May 2001 (21.05.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
2000/0027462 22 May 2000 (22.05.2000) KR
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant (*for all designated States except US*): JUNG-SUNG MEDICAL CO. LTD [KR/KR]; 2F 959-5, Dogok-dong, Gangnam-gu, Seoul 135-270 (KR).
- Published:
— with international search report
- (71) Applicant and
(72) Inventor: YOON, JungHan [KR/KR]; Hyundai Apt. 102-1303, Myungryun-dong, Kangwon, Wonju 220-040 (KR).
- (74) Agent: HWANG, ChongHwan; 5Fl. Yonji Bldg. 831-27 Yoksam-dong, Gangnam-gu, Seoul 135-080 (KR).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: METAL STENT FOR INSERTION IN CORONARY ARTERY



(57) Abstract: The object of this invention is to provide a metal stent used for insertion into a coronary artery to treat a patient suffering from angina pectoris or myocardial infarction due to a coronary artery disease. This stent consists of a plurality of primary stent units (1), each having a zigzag shape rounded at its bent portions and being expandable in a circumferential direction. The primary stent units (1) are assembled into a single cylindrical structure of the stent such that each two primary stent units (1) are integrated into one secondary stent unit by a first strut (2') or (2'') connecting each projected bent portion of each of the two primary stent units (1) to an associated bent portion of the other. Each two secondary stent units are integrated into a desired stent by a plurality of hook-shaped second struts (3) connecting the projected bent portions of the two secondary stent units to each other.



WO 01/89417 A1

METAL STENT FOR INSERTION IN CORONARY ARTERYTechnical Field

The present invention relates, in general, to medical care instruments, or so-called "stents" for insertion in blood vessels and, more particularly, to a coronary care stent made of a metal inserted in the coronary artery to treat a patient suffering from angina pectoris or myocardial infarction due to a coronary artery disease.

Background Art

Coronary artery disease is typically causes ischemia of the heart muscle by involving the coronary artery that is supplying the blood and nutrient to the heart muscle. The most typical etiological factor of such coronary artery diseases is arteriosclerosis. When plaque, formed by the mixing of cholesterol, other lipids, and a variety of components in the coronary artery and deposited on the inner lining of arterial walls, is excessively built up inside of the arterial lumen, the plaque undesirably causes an artery stenosis and ischemia of the heart muscle, thus making the heart muscle suffer lack of oxygen and nutritive substances. In the case of lack of oxygen and nutritive substance to the heart muscle due to ischemia of the heart muscle, a patient suffers angina pectoris or myocardial infarction, which may be fatal.

In the prior art, the non-surgical treatments of patients suffering from such coronary artery diseases use the two types of devices: an expandable balloon catheter or an expandable stent to enlarge the lumen and improve the angina, both being used for non-surgical insertion into a troubled coronary artery.

In the interventional treatment of a coronary artery disease using an expandable balloon, a guiding catheter is primarily inserted into the artery of the femoral region or the arm, and is secondarily positioned at the inlet of the coronary artery having the troubled lesion. In such a case, the term "lesion" means the focus

or the narrowed or stenosed portion of the coronary artery due to built up plaque. After the guiding catheter positioning, a guide wire is navigated down into the coronary artery across the narrowed lesion site under the fluoroscopic guidance. Thereafter, a balloon-tipped catheter is inserted into the coronary artery over or
5 along the guide wire until the catheter positioned at the lesion. The balloon is, thereafter, appropriately expanded to compress the plaque, and expands the narrowed or stenosed vessel to improve the perfusion in the heart muscle.

In case of the interventional treatment using a metallic stent, stent-mounted balloon catheter is inserted at the lesion of a troubled coronary artery
10 after trials of balloon expansion and the balloon catheter with stent mounted is appropriately expanded and deployed at the lesion site. Therefore, the stent is permanently set in the lesion to expand the narrowed or stenosed vessel and allow a smooth circulation of blood in the coronary artery. The interventional treatment using such a stent is an effective treatment, as the stent maintains the expanded
15 state of the vessel for a lengthy period of time. In comparison with the balloon catheter only, the treatment using such a stent reduces the possibility of recurrence of vessel narrowing. In addition, the stent buttresses the inner lining of the coronary arterial walls, and so the stent can be effective for treating a patient suffering from a complication after the procedure.

20 However, atherosclerotic arterial walls around the lesion are typically too rigid, so that they are apt to narrow or be constricted again due to an acute elastic recoil after an angioplasty. Therefore, it is necessary for stents to sufficiently support the arterial wall in a radial direction and maintain the expanded state of the vessels for a desired lengthy period of time.

25 Another expected cause of the re-stenosis of the vessel after an angioplasty using an expandable stent is an excessive proliferation of a neo-intima within the stent. The stent is an in vivo foreign substance, and treatment with an insertion of a stent in the vessel inevitably causes morbid biological injury to the vessel. Therefore, intima is newly, inevitably produced within the vessel inside of
30 the stent. Such a newly produced intima within the vessel is a so-called "neo-intima" in the description of this invention. Such a production of the neo-intima

within the stent after an angioplasty using the stent is recognized as a normal healing response after injury. However, in the case of about 20 ~ 30% of patients of the angioplasty using the stents, the neo-intima within a stent is excessively produced to cause the re-narrowing of the stented artery.

5 In an effort to effectively overcome such a re-stenosis of vessels due to an excessive production of the neo-intima within the stent, it has been required in the art to propose and use a stent designed for effective application of various anti-proliferative agents, which should reduce the excessive production of the neo-intima after the angioplasty.

10 Disclosure of the Invention

 Accordingly, the present invention has been made keeping in mind the above problems occurring in the prior art, and an object of the present invention is to provide a coronary care stent, which is made of a metal and is used for deployment in the coronary artery to treat a patient suffering from angina pectoris or myocardial infarction due to a coronary artery disease, and which is reduced in
15 its profile, in addition to having improved flexibility, improved sidebranch accessibility, larger interstrut spaces, and enhanced radial support force, different from conventional stents, and which is desirably enlarged in its surface area to allow an effective application and preservation of a sufficient amount of anti-
20 intimal proliferation agents to the inner lining of the arterial walls after an angioplasty using the stent, and which effectively transfers the agent(s) to the inner lining of the arterial wall around the lesion having the stent, and allows the topical agent(s) to remain in the vicinity of the lesion for a desired lengthy period of time.

 In order to accomplish the above object, the present invention provides a
25 metal stent used for insertion in a coronary artery, comprising: a plurality of primary stent units each having a zigzag shape, rounded at its bent portions and being expandable in a circumferential direction, the primary stent units being assembled into a single cylindrical structure of the stent such that each two primary stent units are integrated into one secondary stent unit by a first strut connecting

each projected bent portion of each of the two primary stent units to an associated dented bent portion of the other, and each two secondary stent units are integrated into a desired stent by a plurality of hook-shaped second struts connecting the projected bent portions of the two secondary stent units to each other.

5 Brief Description of the Drawings

The above and other objects, features and other advantages of the present invention will be more clearly understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

10 Fig. 1 is a view, showing two primary stent units, each having a modified zigzag shape, in accordance with the preferred embodiment of the present invention;

Fig. 2a is a view, showing a secondary stent unit formed by integrating the two primary units of Fig. 1 together into a single structure using a plurality of straight connecting struts in accordance with an embodiment of this invention;

15 Fig. 2b is a view, showing a secondary stent unit formed by integrating the two primary units of Fig. 1 together into a single structure using a plurality of spoon-shaped connecting struts in accordance with another embodiment of this invention;

20 Fig. 3a is a view, showing a stent formed by integrating two secondary units of Fig. 2b together into a single structure using a plurality of hook-shaped connecting struts in accordance with an embodiment of this invention;

Fig. 3b is a view, showing a stent formed by integrating two secondary units of Fig. 2a together into a single structure using a plurality of hook-shaped connecting struts in accordance with another embodiment of this invention;

25 Fig. 4 is a perspective view of the expandable stent, consisting of a plurality of primary stent units of this invention integrated into a single structure using the straight connecting struts;

Fig. 5 is a perspective view of the stent of Fig. 4 when the stent is expanded to accomplish a desired diameter;

Fig. 6a is a plan view of a connecting strut having a continuous axial groove formed along the central axis of the surface of the strut in accordance with an embodiment of the present invention; and

5 Fig. 6b is a plan view of a connecting strut having a plurality of grooves or holes formed along the surface of the strut in accordance with another embodiment of the present invention.

Best Mode for Carrying Out the Invention

Reference now should be made to the drawings, in which the same reference numerals are used throughout the different drawings to designate the
10 same or similar components.

As shown in Figs. 1, 2a and 2b, the coronary care stent of this invention comprises a plurality of primary stent units 1, each having a modified zigzag shape rounded at its bent portions and being expandable in a circumferential direction, and a plurality of first connecting struts used for integrating two primary units 1
15 together into a single structure to form a secondary stent unit.

In the coronary care stent of this invention, the modified zigzag structure of each primary stent unit 1 allows the unit 1 to be expandable in a circumferential direction when the stent is expanded. The primary stent units 1 thus enlarge the diameter of the stent in the case of an expansion of the stent. In the present
20 invention, it is preferable to set the thickness of each primary stent unit 1 to 0.05mm ~ 0.07mm.

In order to produce a desired stent using the primary stent units 1 of this invention, two primary stent units 1 having the same shape are parallelly arranged prior to integrating the two primary units 1 together into a secondary stent unit using a plurality of first struts. In such a case, the first struts connect the projected
25 bent portions of each of the two primary units 1 to the dented bent portions of the other. In the present invention, a plurality of straight struts 2' of Fig. 2a or a plurality of spoon-shaped struts 2'' of Fig. 2b may be used as the first connecting struts used for forming a desired secondary stent unit by connecting two primary

stent units 1. It is also preferable to set the thickness of each first connecting strut 2' or 2'' to 0.05mm ~ 0.07mm, and the width of each strut 2' or 2'' to 0.05mm ~ 0.15mm. In addition, the total length of each secondary stent unit is preferably set to 6mm ~ 7mm.

5 In order to allow the stent of this invention made of such secondary stent units to easily and smoothly reach a target lesion of a coronary artery, in addition to compensating for a reduction in the total length of the stent during an expansion of the stent within the coronary artery, two secondary stent units are integrated into a single structure using a plurality of second connecting struts 3 having a hook
10 shape as shown in Figs. 3a and 3b, thus forming a desired stent. In such a case, the hook-shaped second struts 3 connect the projected bent portions of the two secondary stent units to each other.

 In order to improve the flexibility of a resulting stent, the hook-shaped second struts 3, used for connecting two secondary stent units to each other into a
15 desired stent, preferably have a width of 2/3 of the width of the first struts 2' or 2'' used for connecting the primary stent units 1 to each other into a secondary stent unit. It is also preferable to set the gap between two secondary stent units in a stent to 0.5mm ~ 1.0mm.

 In the present invention, the cylindrical stent of this invention, having the
20 above-mentioned structure as best seen in Fig. 4, is preferably made of stainless steel or shape-memory alloy through a laser cutting process. When the cylindrical stent is fully expanded through a balloon-added expansion process or a self-expansion process, the diameter of the expanded stent becomes 2.5mm ~ 5.0mm. In such a case, the total length of the fully expanded stent becomes 6mm
25 ~ 47mm. The shape of the fully expanded stent is shown in Fig. 5.

 In order to more effectively inhibit an excessive proliferation of a neo-intima within the stent after an angioplasty, it is necessary for the coronary care stent to allow an effective application of a sufficient amount of anti-intimal proliferation agents to the inner lining of the coronary artery at a position around
30 the stent, and for the applied agents to remain around the stent for a desired lengthy period of time. Known examples of such anti-intimal proliferation

agents, capable of inhibiting an excessive proliferation of the neo-intima after an angioplasty, are anti-cytokinetic agents, such as Paclitaxel, antiplatelet agents, such as Cilostazol, anti-inflammatory agents, and anticoagulant agents. In addition, it is preferable to form the coronary care stent to have a thin sidewall, of which the thickness does not exceed a predetermined level. In order to accomplish the above objects, it is preferable to design the first and second struts for the primary and secondary stent units such that the struts each have a hole or a U-shaped cross-sectioned groove. In the present invention, when it is desired to form the groove or hole in a continuous profile, it is preferable to form a U-shaped cross-sectioned continuous axial groove along the central axis of the strut's surface through a laser cutting process as shown in Fig. 6a. On the other hand, when it is desired to form the groove or hole in a discontinuous profile, it is preferable to form a plurality of holes or a plurality of U-shaped cross-sectioned grooves along the central axis of the strut's surface through a laser cutting process as shown in Fig. 6b. That is, the desired cross-section of the first and second struts may be formed by a continuous axial groove, or a plurality of discontinuous grooves or holes on the strut's surface as desired. In the present invention, the arrangement of the discontinuous grooves or holes on the strut's surface is not limited to the embodiment of Fig. 6b, but may be somewhat freely changed as desired without affecting the functioning of this invention. For example, the discontinuous grooves or holes may be arranged on the strut's surface in a straight arrangement or a zigzag arrangement. In the present invention, it is preferable to set the depth of the continuous groove or the discontinuous grooves of the strut to 0.02mm ~ 0.04mm, and the width to 0.03mm ~ 0.05mm.

Since the first and second struts included in the coronary care stent of this invention have the above-mentioned grooves or holes forming a desired cross-section of each strut, a polymer-based anti-intimal proliferation agent mixture is effectively applied to and more reliably retained by the struts for a desired lengthy period of time without increasing the thickness of the cylindrical stent's sidewall, different from conventional stents.

Industrial Applicability

As described above, the present invention provides a coronary care stent, which is made of a metal and is used for insertion into the coronary artery to treat a patient suffering from angina pectoris or myocardial infarction due to a coronary artery disease. The stent of this invention is specifically designed such that it has sufficient radial support force capable of effectively maintaining the expanded state of the vessel after an angioplasty, different from conventional stents. The stent is also reduced in its thickness, in addition to having improved flexibility, improved sidebranch accessibility, and larger interstrut spaces. This stent is desirably enlarged in its surface area to allow an effective application and retention of a sufficient amount of anti-intimal proliferation agents after an angioplasty using the stent for a desired lengthy period of time. That is, the connecting struts included in the coronary care stent of this invention have continuous or discontinuous grooves or holes forming a desired cross-section of each strut, and so a polymer-based anti-intimal proliferation agent mixture is effectively applied to and reliably retained by the struts for a desired lengthy period of time without increasing the profile of the cylindrical stent. Therefore, the stent of this invention effectively prevents the vessel from being narrowed or constricted again after an angioplasty using the stent, in addition to inhibiting a proliferation of neo-intima within the vessel having the stent, different from the conventional stents.

Although the preferred embodiments of the present invention have been disclosed for illustrative purposes, those skilled in the art will appreciate that various modifications, additions and substitutions are possible, without departing from the scope and spirit of the invention as disclosed in the accompanying claims.

Claims

1. A metal stent for insertion in a coronary artery, comprising:
a plurality of primary stent units each having a zigzag shape rounded at its bent portions and being expandable in a circumferential direction, said primary
5 stent units being assembled into a single cylindrical structure of the stent such that each two primary stent units are integrated into one secondary stent unit by a first strut connecting each projected bent portion of each of the two primary stent units to an associated dented bent portion of the other, and each two secondary stent
10 units are integrated into a desired stent by a plurality of hook-shaped second struts connecting the projected bent portions of the two secondary stent units to each other, each of said first and second struts having a hole on its surface.
2. The metal stent according to claim 1, wherein said first strut connecting the primary stent units to each other is a straight strut.
3. The metal stent according to claim 1, wherein said first strut connecting
15 the primary stent units to each other is a spoon-shaped strut.
4. The metal stent according to any one of claims 1 to 3, wherein said first strut connecting the primary stent units to each other has a thickness of 0.05mm ~ 0.07mm, and a width of 0.05mm ~ 0.15mm.
5. The metal stent according to claim 1, wherein each of the secondary
20 stent units has a total length of 6mm ~ 7mm.
6. The metal stent according to claim 1, wherein each of said hook-shaped second struts connecting the two secondary stent units to each other has a width of 2/3 of a width of said first strut.
7. The metal stent according to claim 1, wherein the two secondary stent

units are arranged with a gap of 0.5mm ~ 1.0mm between them.

8. The metal stent according to claim 1, wherein the stent is expandable through a balloon-added expansion process or a self-expansion process.

5 9. The metal stent according to claim 1, wherein the stent has a diameter of 2.5mm ~ 5.0mm and a total length of 7mm ~ 39mm when it is fully expanded.

10. The metal stent according to claim 1, wherein each of said first and second struts has a U-shaped cross-sectioned groove on its surface.

11. The metal stent according to claim 10, wherein said U-shaped cross-sectioned groove is a continuous groove.

10 12. The metal stent according to claim 1 or 10, wherein said hole or U-shaped cross-sectioned groove is a discontinuous hole or groove.

13. The metal stent according to claim 10 or 11, wherein said groove has a depth of 0.02mm ~ 0.04mm and a width of 0.03mm ~ 0.05mm.

15 14. The metal stent according to claim 1, wherein the stent is made of a stainless steel or a shape-memory alloy.

$\frac{1}{4}$

FIG. 1

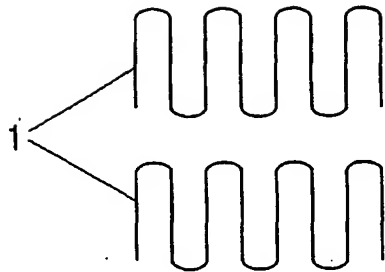


FIG. 2a

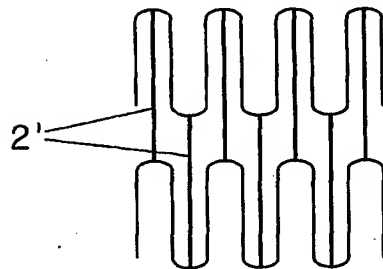
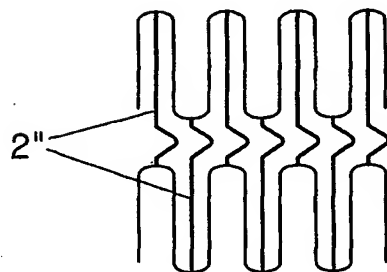


FIG. 2b



2/4

FIG. 3a

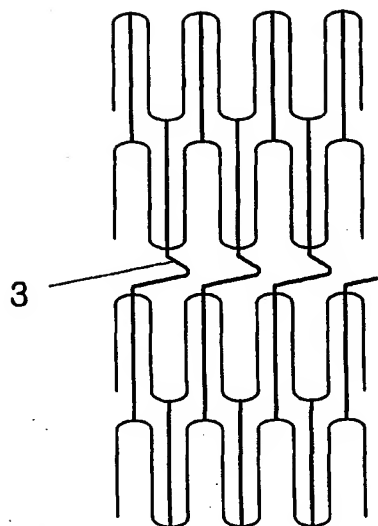


FIG. 3b

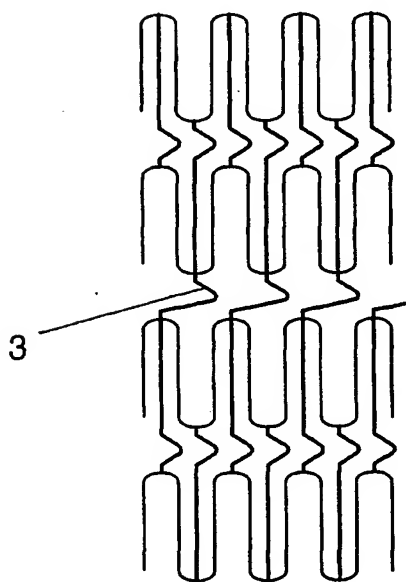


FIG. 4

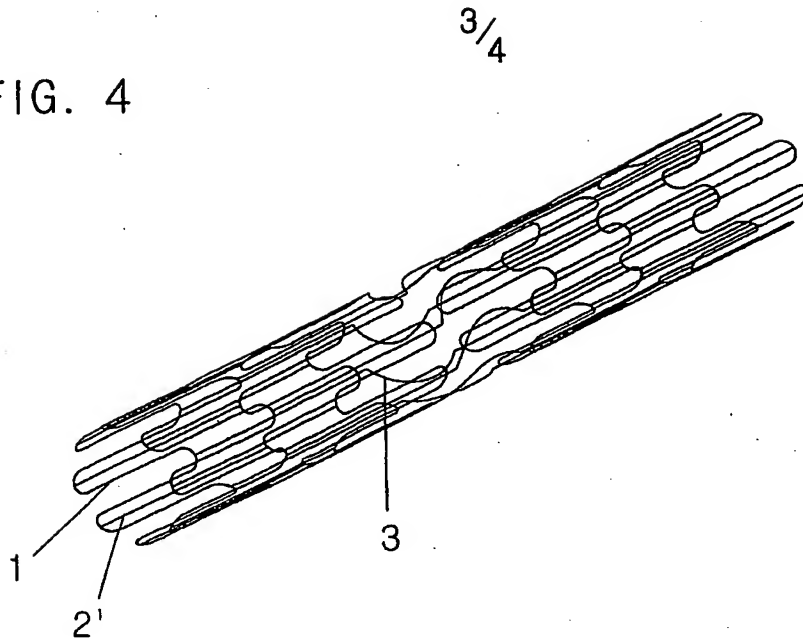
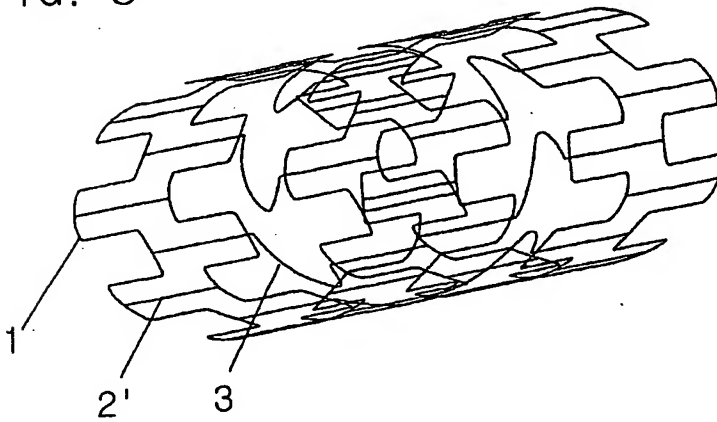


FIG. 5



4/4

FIG. 6a

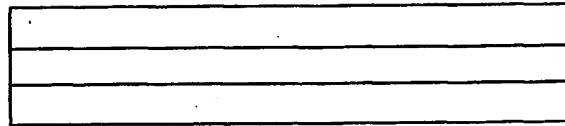
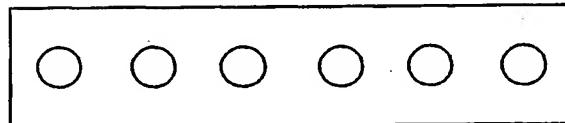


FIG. 6b



INTERNATIONAL SEARCH REPORT

International application No.

PCT/KR01/00833

A. CLASSIFICATION OF SUBJECT MATTER

IPC7 A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7 A61B 17/00, A61F 2/06, A61M 29/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WIPS, NPS, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6013854 A (TERUMO CO., LTD) 11 JANUARY 2000 See patent abstract and figures	1-14
Y	US 5443496 A (MEDTRONIC, INC) 22 AUGUST 1995 See claim 1 and figure 10, 11 and 14	1-14
A	US 5735871 A (JEAN-CLAUDE, SGRO) 7 APRIL 1998 See the whole documents	1-14

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

22 AUGUST 2001 (22.08.2001)

Date of mailing of the international search report

23 AUGUST 2001 (23.08.2001)

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
Government Complex-Daejeon, Dunsan-dong, Seo-gu, Daejeon
Metropolitan City 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

KIM, Seung Soo

Telephone No. 82-42-481-5581



INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/KR01/00833

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6013854 A	11.01.00	EP 688545 A	27.12.95
		JP 08-000738 A	09.01.96
US 5443496 A	22.08.95	US 5651174 A	29.07.97
US 5735871 A	07.04.98	EP 715834 A	12.06.96
		FR 2727854 B	07.02.97